K032926

510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared:	19 September 2003
Submitter:	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432
Contact:	Kristyn M. Benson Regulatory Affairs Specialist
Telephone:	(763) 514-4617
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E-mail:	kristyn.m.benson@medtronic.com
Proprietary Name:	Paceart® System
Common Name:	Pacemaker Waveform Analyzer and Digital Electrocardiograph
Device Classification:	Class II, 21 CFR § 870.2340, 870.2920, 870.3640
Product Codes:	DPJ, DXH, KRE

Device Description

The Medtronic Paceart® System is a personal computer based pacemaker-testing system, a 12-lead electrocardiograph, and a transtelephonic receiving station. It provides data that can be used to analyze implanted pacemaker performance based on electrocardiographic measurements, either taken directly from the patient or programmer. The system can measure, store, and display any of the 12 standard leads. Reports and charts are available by means of a laser printer. The system also includes a database that collects and stores patient data. Optional software allows the device to function as an unattended transtelephonic receiving station.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Ms. Kristyn M. Benson
Regulatory Affairs Specialist
Medtronic, Inc.
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K032926
Trade Name: Paceart® System EKG Speaks™
Regulation Number: 21 CFR 870.3640
Regulation Name: Indirect Pacemaker Generator Function Analyzer
Regulatory Class: Class II (two)
Product Code: KRE
Dated: September 19, 2003
Received: September 22, 2003

Dear Ms. Benson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number if known: N/A

Device Name: Paceart System – EKG Speaks™

Indications For Use: The Paceart System is intended for use as a 12-lead electrocardiograph, pacemaker artifact analyzer, and transtelephonic ECG monitor. It also acts as a database for pacemaker and implantable cardioverter defibrillator patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032926

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)